

Follow-up No.

BILAG Biologics Register Consultant Follow-up Questionnaire

Number of months post treatment (please circle below)

0	3	6	12	24	36
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Biologic treatment number (please circle below) (if applicable)

1	2	3	4	5
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Centre ID:

Consultant:

PATIENT ID:

Today's Date:

Biologic therapy

On _____ your patient was on _____ <insert biologic drug>

1. Since that date, have there been any changes to the patient's biologic therapy (including any new biologic drugs)?

Yes ☐ No ☐

2. Please record all changes for biologic agents (please use trade names):

Drug	Dose	Date started (dd/mm/yy)	Date of final dose (dd/mm/yy)	If this is a drug discontinuation, list reason here

Discontinuation code: 1 = Inefficacy; 2 = remission; 3 = Adverse events; 4 = Other*

*If your patient has had an "adverse event" or "other" reason leading to drug discontinuation, please give details, including which drug, here:

Is the patient switching from an originator i.e. Mabthera directly to a biosimilar of the same product i.e. Truxima? ☐ Yes ☐ No

If yes, please provide the reason for the switch:

<input type="checkbox"/>	Clinical Indication
<input type="checkbox"/>	Patient Choice
<input type="checkbox"/>	Cost Factors
<input type="checkbox"/>	Other:

Comments:

Please complete below if patient is a CONTROL GROUP PARTICIPANT
Immunosuppressants

On _____ your patient was on _____ [immunosuppressant(s)]

Since that date, have there been any changes to the patient's immunosuppressant therapy? Yes ☐ No ☐
Please record all changes for immunosuppressant therapy:

1. Azathioprine; 2. I.V. Cyclophosphamide; 3. Cyclophosphamide P.O.; 4. Methotrexate; 5. Cyclosporin A;
6. Mycophenolate Mofetil; 7. Other (please specify)

Drug Code	Date started	Date finished	Average dose	Reason for discontinuation*

*Discontinuation code: 1 = Inefficacy; 2 = remission; 3 = Adverse events; 4 = Other – please specify

Please complete below for ALL STUDY PARTICIPANTS

Steroids

On _____ your patient was on _____ [steroid(s)]

Since that date, have there been any changes to the patient's steroids? Yes ☐ No ☐
Please record all changes for steroids:

Drug	Date started	Date finished	Average dose	Reason for discontinuation*

*Discontinuation code: 1 = Inefficacy; 2 = remission; 3 = Adverse events; 4 = Other – please specify

Please complete below for ALL STUDY PARTICIPANTS

Concomitant medication

Information was last collected on _____ [date]

Since that date, have there been any changes in the patient's medication, not mentioned above?

Please record all changes for medication:

Yes ☐ No ☐

Drug	Date started	Date finished	Average dose	Reason for discontinuation*

*Discontinuation code: 1 = Inefficacy; 2 = remission; 3 = Adverse events; 4 = Other

Please complete below for ALL STUDY PARTICIPANTS

Covid-19 vaccinations:

Has the patient received a Covid-19 vaccination since the last follow up? Yes ☐ No ☐ Don't know ☐

Did the patient have both doses? Yes ☐ No ☐ Don't know ☐

Date of most recent dose (approx. if necessary): (DD/MM/YYYY)

Covid-19 vaccine brand: ☐ Pfizer/Biontech,
☐ Oxford/Astra Zeneca
☐ Moderna
☐ Unknown
☐ Other not listed:

Adverse Events / New Medical Diagnoses:

Since _____ has this patient experienced any new illnesses or adverse events (whether or not related to any medication)?

Yes ☐ No ☐

We are particularly interested in the following key incidents of interest:

- Any infections
- Any malignancy
- Hospitalisation (for any reason)
- Pregnancy
- Operation (for any reason)
- Antibiotic courses
 - Out patient
 - In-patient

Adverse Event / New Illness #1 _____ **Date** _____

Was the patient on a biologic agent at the time of the new event / illness? Yes ☐ No ☐

Did the event result in death / hospital admission / IV antibiotics / significant loss of function or disability / congenital malformation / or was in any other way life threatening? (please circle where appropriate)

Yes ☐ No ☐

Details _____

Do you think that there is a reasonable possibility that this event was related to the patient's biologic therapy?

Yes ☐ No ☐

Was a Yellow Card filled in for the new event / illness?

Yes ☐ No ☐

Adverse Event / New Illness #2 _____ **Date** _____

Was the patient on a biologic agent at the time of the new event / illness? Yes ☐ No ☐

Did the event result in death / hospital admission / IV antibiotics / significant loss of function or disability / congenital malformation / or was in any other way life threatening? (please circle where appropriate)

Yes ☐ No ☐

Details _____

Do you think that there is a reasonable possibility that this event was related to the patient's biologic therapy?

Yes ☐ No ☐

Was a Yellow Card filled in for the new event / illness?

Yes ☐ No ☐

Adverse Event / New Illness #3 _____ **Date** _____

Was the patient on a biologic agent at the time of the new event / illness? Yes ☐ No ☐

Did the event result in death / hospital admission / IV antibiotics / significant loss of function or disability / congenital malformation / or was in any other way life threatening? (please circle where appropriate)

Yes ☐ No ☐

Details _____

Do you think that there is a reasonable possibility that this event was related to the patient's biologic therapy?

Yes ☐ No ☐

Was a Yellow Card filled in for the new event / illness?

Yes ☐ No ☐

If your patient has experienced more than three events / illnesses, please include details as above on a separate sheet.

ADVERSE EVENTS OF SPECIAL INTEREST

IF ANY OF THE ADVERSE EVENTS YOU HAVE LISTED INCLUDE ONE OF THE FOLLOWING:

- **SERIOUS INFECTION REQUIRING HOSPITALISATION**
- **INFUSION REACTION**
- **IMMUNOGLOBULIN DEFICIENCY**
- **PREGNANCY**

Please ensure you have provided all the information you have available for these events, by completing the relevant Event of Special Interest (ESI) form, continuing on a separate sheet if necessary.

This form should be accompanied by the following completed forms

- | | |
|--------------------------|--|
| <input type="checkbox"/> | BILAG 2004 index |
| <input type="checkbox"/> | SLEDAI 2K |
| <input type="checkbox"/> | SLICC damage index (only at 12, 24 and 36 months) |

Name of Person Completing Form: _____

Contact Telephone Number: _____

Date Form Completed: _____

Patient Vital Status

Alive ☐

Dead ☐

Date of Death: _____